



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0424]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements under the Postmarketing Safety Reporting Rule for Combination Product for Constituent Part Applicants to share specified adverse event information with one another.

DATES: Submit either electronic or written comments on the collection of information by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL***

REGISTER]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2008-N-0424 for "Postmarketing Safety Information Sharing by Constituent Part Applicants for Combination Products." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as

"confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Information Sharing Among Constituent Part Applicants--21 CFR 4.103

OMB Control Number 0910-0834--Extension

This information collection request applies to "constituent part applicants" as defined under 21 CFR 4.101 (i.e., any person holding an application under which a constituent part (drug, device, or biological product) of a combination product received marketing authorization if the other constituent part(s) received marketing authorization under an application held by a different person). Under this collection, constituent part applicants must share safety information they receive related to certain events with the other constituent part applicant(s) and maintain associated records.¹

FDA estimates the burden of this collection of information as follows:

¹ The Postmarketing Safety Reporting (PMSR) information collections for drugs, biological products, and devices found in §§ 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20 (21 CFR 314.80, 314.81, 600.80, 600.81, 606.170, 606.171, 803.50, 803.53, 803.56, 806.10, and 806.20) have already been approved and are in effect or their extension is being sought separately as required, including with respect to burden for combination products (reflected in the authorization for OMB control number 0910-0834, but, therefore, not addressed in this extension request). The pertinent PMSR information collection provisions for § 314.80(c) and (e), as well as for § 314.81(b) are approved under OMB control numbers 0910-0001, 0910-0230, and 0910-0291. The information collection provisions for §§ 600.80 and 600.81 are approved under OMB control number 0910-0308. Those for § 606.170 are approved under OMB control number 0910-0116. Those for § 606.171 are approved under OMB control number 0910-0458. The information collection provisions for §§ 803.50, 803.53, and 803.56 are approved under OMB control numbers 0910-0291 and 0910-0437. The information collection provisions for §§ 806.10 and 806.20 are approved under OMB control number 0910-0359.

Table1.--Estimated Annual Third-Party Disclosure and Recordkeeping Burden

21 CFR Section/ Activity	No. of Respondents/ Recordkeepers	No. of Disclosures/Records per Respondent/ Recordkeeper	Total Annual Disclosures/ Records	Average Burden per Disclosure/ Recordkeeping	Total Hours
4.103, Sharing information with other constituent part applicants	33	18	594	0.35 (21 minutes)	208
4.103(b) and 4.105(a)(2), Records of information shared by constituent part applicants	33	18	594	0.1 (6 minutes)	59
Total					267

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. We note in this regard that FDA extended the compliance date for 21 CFR part 4, subpart B, until July 2020 for most combination products, and until January 2021 for the remainder, in response to stakeholder feedback, to ensure that Combination Product Applicants have sufficient time to update reporting and recordkeeping systems and procedures.² Consequently, entities subject to this rule have not yet had to comply with this information request.

Dated: April 23, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

² See Compliance Policy for Combination Product Postmarketing Safety Reporting (April 2019) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/compliance-policy-combination-product-postmarketing-safety-reporting>).

